

domains including 93 items. We enhanced our previous selection of only European HTA agencies (IQWiG, DAHTA@DIMDI, NICE, HAS, SBU) by AHRQ, MSAC, LBI, BIQG / GOGG, CADTH, DECIT-CGATS, HITAP. Information was collected and compared quantitatively, choosing the item 'cost-effectiveness threshold' as key information. Additionally, HTA agencies' methodological guidelines were extracted for PCM relevant information. Finally, information was entered into the database and compared qualitatively. **RESULTS:** First five agencies differed highly in eight domains (organization scope, processes, methods, dissemination, decision, implementation, and impact). They agreed in only 17-40%. Enhancement by further agencies indicates continued heterogeneity. UK (US\$32,000-48,000) and Thailand (US\$9,866) indicated explicit but generic (i.e. not specific to disease or type of technologies) thresholds; implicit use was identified in five countries (Australia, Brazil, Canada, Sweden, USA). Germany explicitly uses disease-specific cost-effectiveness ratios. In none of the included countries cost-effectiveness thresholds specific to personalized medicine and/or oncology were identified, even though we found exception rules in UK. **CONCLUSIONS:** Based on a systematic and comprehensive contextual framework displaying HTA in 10 countries of four continents we identified large heterogeneity in the application of HTA. Specific guidance for innovative and costly cancer interventions is lacking.

PHP125

CLINICAL TRIAL LEARNING CURVES MAY IMPACT BOTH CLINICAL AND ECONOMIC OUTCOMES, AND INFLUENCE HEALTH TECHNOLOGY ASSESSMENT AND REIMBURSEMENT DECISION MAKING

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OBJECTIVES: We previously presented evidence suggesting that clinical trial learning curves may affect clinical outcomes in patients in drug trials. In the current analysis, we demonstrate the potential effect of learning curves on economic outcomes (specifically, cost-effectiveness). **METHODS:** The PROWESS trial, which evaluated drotrecogin alpha (DrotAA) for severe sepsis, was identified in our previous study and was chosen for further analysis based on several considerations: a published analysis suggested that a clinical trial learning curve may have had a substantial effect on outcomes in a subgroup of patients (APACHE II < 25); and a published cost-effectiveness analysis (which did not account for the learning curve effect) was transparent and easily replicable. Furthermore, a health technology appraisal (HTA) of DrotAA conducted in the UK cited the cost-effectiveness analyses, which suggested that the incremental cost per quality-adjusted life year for patients with APACHE II scores < 25 was > US\$400,000. Similarly, an Australian reimbursement decision excluded this patient subpopulation from coverage citing unacceptable cost-effectiveness. We replicated the cost-effectiveness analysis for DrotAA, and used it to model the cost-effectiveness of DrotAA in the subgroup of patients with APACHE II < 25, both with and without the patients enrolled earlier in the trial and thus potentially affected by the learning curve. **RESULTS:** When patients who may have been affected by the trial learning curve were excluded from the analysis, cost-effectiveness of DrotAA improved significantly, from US\$411,333 per LYG with all patients with APACHE II score < 25 to US\$46,395 per LYG when the first block of patients enrolled at each site was removed from the analysis. **CONCLUSIONS:** Clinical trial learning curves potentially affect both clinical and economic outcomes, and impact reimbursement decisions. Consideration of learning curves may be important in HTAs and reimbursement decisions, particularly when evaluating trial data in which learning curves are more likely to be present.

PHP126

OVERVIEW OF HTA PROCESS AND IMPLEMENTATION AMONG HEALTH STAKEHOLDERS IN BOSNIA AND HERZEGOVINA – SURVEY BASED RESEARCH

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OBJECTIVES: Health Technology Assessment (HTA) is relatively new concept for Bosnia and Herzegovina health care decision-makers. Decision on reimbursement of medicines and other technologies are made on different levels due to decentralized health system and by different stakeholders (Entities/Cantonal Health Insurance Funds-HIF, Hospitals, Ministries of Health-MoH). Objective of this survey was screening of current situation and understanding of HTA principles, process and implementation in decision making process among key stakeholders. **METHODS:** A 9-question survey with INAHTA definition of HTA provided has been distributed to 50 stakeholders with potential influence on reimbursement decisions. Survey include questions on current practices and process of reimbursement decisions, existence of HTA body/commission, criteria for decisions and reasons for de-listing of reimbursed technologies. Deadline for response was two months. **RESULTS:** Overall response rate was 30%; 50% (6/12) of Ministries of Health, 42% (5/12) Health Insurance Funds and 17% (4/24) Hospitals respond. 73% respondents use criteria for decisions on drug reimbursement, and 67% in case of other technologies. Mostly used criteria are expert opinions (47%) and pharmacoeconomic studies provided by the manufacturer/presentative (40%), while 33% use referral pricing as criteria. Most of respondents use mixed criteria. HTA bodies in form of commission/expert boards are established in 7 institutions, mostly in MoH and HIFs. These bodies consist of physicians and pharmacists, and only two of respondents include economist into these bodies. Similar situation is observed in case of medical devices and other technologies reimbursement decisions. De-listing is recorded in 40% respondents but main reason was production discontinuation. **CONCLUSIONS:** Although the response rate is low, it allows conclusions that correlate with the experience and current practices. There is a need for a systematic

approach to HTA and adoption of clearer criteria for reimbursement decision-making. Establishing HTA bodies consisted of trained professionals would improve the HTA process and reimbursement decisions.

PHP127

IMPACT OF PATIENT ACCESS SCHEMES ON NICE AND SMC GUIDANCE

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OBJECTIVES: To determine whether the use of patient access schemes (PAS) in the provision of NICE and SMC guidance could be brought into greater alignment, leading to greater cost savings. **METHODS:** From a survey of technology appraisals published on the SMC and NICE websites, the total number involving a PAS has been assessed. Further, if a PAS is included for a particular drug in one set of guidance, a comparison has been made of the equivalent guidance by the other body. There are differences between NICE and SMC roles: NHS England should fund/resource treatments recommended by NICE; NHS Scotland is expected to consider SMC advice, but it is not binding. SMC issues guidance on all newly licensed medicines, unlike NICE, which prioritizes guidance where it is most needed. **RESULTS:** The list of positive NICE appraisals based on the inclusion of a PAS consists of 15 pharmaceuticals, while the same list for the SMC includes only nine. Most products with a PAS are included in both sets of guidance, with seven of the nine SMC PAS also included in the NICE guidance. The remaining two with SMC PAS have not been assessed by NICE. Of eight NICE PAS not included in SMC guidance, four were accepted/accepted with restricted use, e.g. lenalidomide. The NICE PAS ensures that if a patient receives >26 treatment cycles, the manufacturer will cover the cost of further cycles. No PAS is included in SMC guidance; therefore, NHS Scotland has no cost cap. **CONCLUSIONS:** PAS are more frequently included in manufacturers' submissions to NICE than to SMC. SMC has approved a number of therapies for which NICE required a PAS to improve the economic argument. Therefore, for these drugs, NHS Scotland could potentially achieve greater cost savings if SMC demanded similar PAS to those required by NICE.

PHP128

IN DEPTH ANALYSIS OF HEALTH TECHNOLOGY INCORPORATION IN BRAZIL. IS THERE A COST-EFFECTIVENESS MEASURE OF THRESHOLD?

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OBJECTIVES: Recently, a study conducted in Brazil (Teich et al, 2010) evaluated the decisions and process submitted to the Brazilian Commission on Health Technology Incorporation (CITEC), classifying them according to therapeutic area, response type and applicant. The study concluded that there is no clear definition of priorities for the incorporation of a new technology; however, it did not analyze a possible cost-effectiveness threshold for decision making. Therefore, the present study aims to evaluate the existence of economic analysis which supports CITEC decisions and map possible trends. **METHODS:** CITEC decisions and technologies for analysis were obtained from the updated list available at the Ministry of Health website. Only economic studies (cost-effectiveness/utility, cost-minimization and budget impact) from the Brazilian perspective were included and the following databases were consulted: "Medline", "SciSearch", "Embase", "Biosis Preview" and "ISPOR Outcomes Research Digest". **RESULTS:** Technologies were classified in 3 categories: incorporated, not-incorporated and in-analysis; and the results from economic evaluations were classified into: dominant /cost-saving; up to \$Brz30,000; \$Brz30,000-50,000; \$Brz50,000-100,000 and above \$Brz100,000 per outcome (ideally QALY or LY, but others were considered). Of the technologies that were not-incorporated, only 2 presented economic evaluation from Brazilian perspective: 1 study with incremental cost up to \$Brz30,000 and 1 between \$Brz50-100,000. From incorporated technologies, only 20% presented economic evaluations with results belonging to all categories (including above \$Brz100,000 per outcome). From technologies in analysis, 20% had economic studies, being most of them dominant or cost-saving. **CONCLUSIONS:** Apparently, there is no criterion for health technology assessment and inclusion of new technologies in Brazilian public system (SUS) and also a lack of quality in the economic analysis conducted. Therefore, besides the absence of priorities, the absence of criteria for technology incorporation could potentially lead the system to be inefficient, spending more money than necessary and not adopting cost-saving therapies.

PHP129

SOCIETAL PREFERENCES FOR HEALTH TECHNOLOGY DISINVESTMENT POLICY: VIEWS OF SCOTTISH TAXPAYERS – A QUALITATIVE STUDY

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OBJECTIVES: Increasingly challenging economic times require challenging decisions to be made regarding health technology disinvestment. Insufficient evidence exists on societal preferences for disinvestment in publicly-funded health care systems. This research sought to explore the acceptability of disinvestment to Scottish taxpayers, their preferences, and whether taxpayer loss aversion is a relevant factor for disinvestment policy development. **METHODS:** Qualitative interviews were conducted with a sample of Scottish taxpayers. Interviews were split into four parts to progress thematic discussion from basic to complex, examine consistency and identify responses potentially indicative of loss aversion. Participants were asked about their general views on the NHS and disinvestment (Part 1), scenario-based questions on disinvestment (Part 2), to freely discuss the disinvestment issues they considered important and who they thought should be involved in making decisions (Part 3), and further scenario-based questions on health technology investment (Part 4). **RESULTS:** Twelve interviews were undertaken. Responses were generally consistent. Scottish taxpayers notionally accepted disin-